Louisiana Medicaid
Infectious Disorders – Antibiotics - Oxazolidinones

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for linezolid (Zyvox®) and tedizolid phosphate (Sivextro®).

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Linezolid (Zyvox®)

Approval Criteria

- The recipient's *diagnosis and pathogen* for which linezolid is being prescribed is **stated on the request** and is included in the table below [See **Table 1. Linezolid Covered Indications with Dosage, Route, and Frequency by Indication**]; **AND**
- The prescriber **states on the request** that the request is for *new therapy* or *continuation of therapy*. For outpatient continuation after inpatient initiation, *dosage and date ranges of inpatient use* of linezolid must be **stated on the request**; **AND**
- To reduce the development of drug-resistant pathogens and to maintain the effectiveness of linezolid, special considerations related to antibiotic resistance must be addressed in requests for linezolid.
    - Antibiotic resistance to all other appropriate therapies must be demonstrated by culture and sensitivity (provide C & S report); **OR**
    - Antibiotic resistance must be demonstrated by a history of antibiotic use (provide documentation of previous antibiotic treatment trials and dates of therapy); **OR**
    - Antibiotic resistance must be suspected due to local sensitivity patterns (provide supporting clinical rationale); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling; **AND**
- If the request is for a non-preferred product, **ALL** of the following are required:

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
  - The prescriber states that the request is to *complete a course of treatment that was initiated while the recipient was in an inpatient facility*.

As outlined above, *prescribers must include a C & S report **OR** documentation of previous antibiotic treatment trials and dates of therapy **OR** supporting clinical rationale with requests for linezolid*.

Duration of approval: Up to 14 days based upon patient-specific factors

Table 1. Linezolid Covered Indications with Dosage, Route, and Frequency by Indication

Covered Infections Due to Susceptible Gram-Positive Bacteria	Pediatric Patients[1] (Birth through 11 Years of Age)	Adults and Adolescents (12 Years of Age and Older)	Duration (Days)[2]
Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*	10 mg/kg intravenous (IV) or oral every 8 hours	600 mg IV or oral every 12 hours	10 to 14
Community-acquired pneumonia caused by *S. pneumoniae*, including concurrent bacteremia, or *S. aureus* (methicillin-susceptible isolates only)			
Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by *S. aureus* (methicillin-susceptible and -resistant isolates). *Streptococcus pyogenes* or *Streptococcus agalactiae*[3]			
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg IV or oral every 8 hours	600 mg IV or oral every 12 hours	14 to 28
Uncomplicated skin and skin structure infections caused by *S. aureus* (methicillin-susceptible isolates only) or *S. pyogenes*	Younger than 5 years: 10 mg/kg oral every 8 hours 5-11 years: 10 mg/kg oral every 12 hours	Adults: 400 mg oral every 12 hours Adolescents: 600 mg oral every 12 hours	10 to 14

1. See prescribing information for dosing in neonates younger than 7 days of age.
2. Duration of therapy is the total of any inpatient days and outpatient days on linezolid (Zyvox®).
3. Zyvox® has not been studied in the treatment of decubitus ulcers.

Tedizolid Phosphate (Sivextro®)

Approval Criteria

- The recipient's *diagnosis and pathogen* for which tedizolid is being prescribed is **stated on the request** and is included in the table below [See **Table 2. Tedizolid Covered Indications with Dosage, Route, and Frequency by Indication**]; **AND**
- The prescriber **states on the request** that the request is for *new therapy* or *continuation of therapy*. For outpatient continuation after inpatient initiation, *dosage and date ranges of inpatient use* of tedizolid must be **stated on the request**; **AND**
- To reduce the development of drug-resistant pathogens and to maintain the effectiveness of tedizolid, special considerations related to antibiotic resistance must be addressed in requests for tedizolid.
    - Antibiotic resistance to all other appropriate therapies must be demonstrated by culture and sensitivity (provide C & S report); **OR**
    - Antibiotic resistance must be demonstrated by a history of antibiotic use (provide documentation of previous antibiotic treatment trials and dates of therapy); **OR**
    - Antibiotic resistance must be suspected due to local sensitivity patterns (provide supporting clinical rationale); **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not be receiving the requested medication in combination with any other medication that is contraindicated or not recommended per FDA labeling; **AND**
- If the request is for a non-preferred product, **ALL** of the following are required:
    - There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
    - Previous use of a preferred product - **ONE** of the following is required:
        - The recipient has had a *treatment failure* with at least one preferred product; **OR**
        - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
        - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
        - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**

- The prescriber states that the request is to *complete a course of treatment that was initiated while the recipient was in an inpatient facility*.

As outlined above, *prescribers must include a C & S report **OR** documentation of previous antibiotic treatment trials and dates of therapy **OR** supporting clinical rationale with requests for tedizolid.*

Duration of approval: Up to 6 days based upon patient-specific factors

Table 2. Tedizolid Covered Indications with Dosage, Route, and Frequency by Indication

Covered Infections and Susceptible Isolates	Adult Patients (12 Years of Age and Older)	Duration
Acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*), and *Enterococcus faecalis.*	200mg intravenously (IV) once daily	6 days
	200mg orally once daily	6 days

References

Sivextro (tedizolid phosphate) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2021.. https://www.merck.com/product/usa/pi_circulars/s/sivextro/sivextro_pi.pdf

Zyvox (linezolid) [package insert]. New York, NY: Pharmacia & Upjohn Co; April 2021. http://labeling.pfizer.com/showlabeling.aspx?id=649

Revision / Date	Implementation Date
Single PDL Implementation	May 2019
Removed Fee-for-Service, added revision table, removed footer, combined all Oxazolidinones into one criteria document / January 2020	January 2020
Formatting changes, updated references / July 2020	July 2020
Updated age for Sivextro®, formatting changes, updated references / May 2021	October 2021